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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,556	06/16/2006	Victor Casana Giner	38438.00.0002	7869

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
12/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,556	CASANA GINER ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,14,23,27,30,34,40,57 and 84-106* is/are pending in the application.

4a) Of the above claim(s) *27,30,34 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,14,23,40,84-106* is/are rejected.

7)☒ Claim(s) *110* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I: claims 1, 5, 14, 23, 40 and 84-110 in the reply filed on 9/14/10 is acknowledged. Applicant election of alginate as the hydrocolloid and Lactobacillus casei as the bacterial species is also acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 97 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 97 recites the limitation "the viscosity modifier" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no viscosity modifier in claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5, 14, 23, 40, 90, 91, 94, 96, 98, 100, 101, 104, 107, 109 and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Mathiowitz et al (USPN 5,985,354 hereafter '354) in view of Brach et al (USPN 4,720,460 hereafter '460).

The '354 patent discloses a microencapsulating process comprising multiple polymer solutions and resulting in microcapsules with multiple polymeric coatings (abstract). An emulsion is formed by emulsifying an aqueous phase comprising a biologically active agent (col. 8, lin. 10-18). The aqueous portion is mixed with an emulsifier to form an emulsion (col. 8, lin. 15, col. 9, lin. 30-35, Examples), where the oil phase can be an organic oil (col. 8, lin. 43; col. 9, lin. 30-35). To this polymeric solutions are added to form layers or coating over the encapsulated core (col. 8, lin. 35-40; col. 11, lin. 25-30). Possible hydrocolloid compounds include gelatin and alginates (col. 4, lin. 45-50). These alginates have an HLB from 10-14. These are not enteric polymers and as such would release in highly acidic conditions less than 3 pH. The aqueous portion can further include polymerization initiators that crosslink the polymers (col. 10, lin. 35-45). The first and second hydrocolloid solutions can be used to polymerize or crosslink each other, for example alginate can be crosslinked with gelatin with the aid of cations metal ions (col. 11, lin. 18-25). The temperature is raided in order to speed the

process, in doing so the layered polymers harden strengthening the outer layers (col. 11, lin. 10-17). Despite the thermal hardening the temperature is maintained between 20-60^{0}C (col. 11, lin. 3-10). Surfactants can be added after the formation of the microcapsules (Examples). The resulting microcapsules are washed and dispersed in ethanol (Examples). The water phase comprises no alcohol and as such comprises less than the 40% required in claim 101.

The reference discloses a wide variety of encapsulated active agents including enzymes and biologically active agents. What is lacking is the specific biologically active materials of the claim 40, the elected compound Lactobacillus casei.

The ‘406 patent discloses a method of stabilizing bacteria compounds (abstract). The stabilization process included microencapsulation where the process comprises stabilizers and carriers such as alginates, xanthan gum and polyethylene glycol (col. 3, lin 60-col. 4, lin. 5). The bacteria include Lactose base bacteria such as Lactobacillus casei (col. 4, lin. 30-45). It would have been obvious to include these compounds into the ‘345 patent in order to further stabilize the compounds, specifically from thermo degradation. It would have been prima facia obvious to combine the prior art since both provide the stabilization of biologically active agents. Including the bacteria of the ‘460 patent would have been prima facia obvious to improve the stability by the process of the '345 patent.

The reference differs from the instant claims in the order of steps in the process. However the same general conditions and major steps have been accomplished. An emulsion is formed comprising a biologically active substance, an oil phase, and water phase comprising polymerization initiators. To this emulsion further hydrocolloid compounds are added and polymerized. The resultant mixture is heated, surfactants are added, and the resultant

microcapsules are suspended in water (examples). It has been held that the selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946). In the instant case the resulting microcapsules are formed with the same steps and as such would be prima facie obvious over the instant claims.

Claims 1, 84-87 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Mathiowitz et al (USPN 5,985,354 hereafter '354) in view of Unger et al (USPN 5,773,024 hereafter '024).

As discussed above the '354 patent discloses a process of making microcapsules. The reference discloses the general steps but is silent to the conditions under which the microcapsules are formed.

The 024 patent discloses a method of making microcapsules (abstract). The microcapsules are formed under constant agitation (col. 11, lin. 60-65) with RPMs from 25-4000 (col. 18, lin. 1-5). The formation occurs in the presence of an inert gas such as nitrogen (col. 6, lin. 58-63) inside of a container that protects the process from light degradation (Figures). The pressure in the container is reduced (Table 2). The emulsion comprises an oil phase where the oil can be soybean oil (col. 13, lin. 25-35). Stabilizers/surface active agents that can be included in the formulation include glycerol esters (col. 14, lin. 21-28). The resulting particles have an average diameter of about 3μm (Table 6). It would have been obvious to process the microcapsules of the '354 container and agitator in order to protect the emulsion from premature photo initiation.

It would have been prima facia obvious to formulate the microcapsules of the '354 patent in the apparatus of the '024 patent in order to protect the components from premature photo-initiation. It would have been obvious to combine the prior art with an expected result of a stable microparticle formulation.

Claims 1, 88, 89, 99, 102, 103, 105, and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Mathiowitz et al (USPN 5,985,354 hereafter '354) in view of Yan et al (US 2003/0193102 hereafter '102).

As discussed above the '354 patent discloses a method of microencapsulation comprising adding colloidal solutions to an emulsion, where the emulsion comprising an oil and water phase. What is lacking is the specific oils of the oil phase and the components of the aqueous phase.

The '102 publication discloses a method for microencapsulation where the microcapsules have an outer shell made of a colloidal compound (abstract). The outer shell coats microcapsules comprising an oil and aqueous phase, wherein the oil can be an omega-3 fatty acid, flax oil and vitamin E [0021]. The outer colloidal shell comprises alginates or arabic gum [0022]. The encapsulated aqueous phase comprises ascorbic acid that aids in the encapsulation process [0024, claim 9]. The microcapsules are dried and formed into a powder for use in food and beverages [0039, claims]. The microcapsules have a particle size from 50-100 μm [0026-0027]. It would have been obvious to combine these various components into the process of the '354 patent since both patents comprise similar components. The oil components would improve the nutritional properties of the resulting microcapsules. The hydrocolloids in the shell would provide stability to the microcapsules provide a stronger rupture-resistant structure that achieves high loads of active substances.

It would have been obvious to combine the prior art in order to provide a more stable and rupture resistant microparticle formulation. This formulation would have increase load capacity and use in food and beverage preparations.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Thursday 7:00-5:30; every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618